

## **REMARKS**

Entry of the above amendments in reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 36-60 and 62 pending and under consideration. It is believed that the above amendments and the following remarks address all outstanding rejections. Thus, allowance of the application is solicited.

Claims 54-60 stand rejected under 35 USC § 112, first paragraph, based upon an assertion that the specification does not contain written description adequate to support the claims. In response, it is believed that this rejection has been rendered moot due to the amendments made to claim 54. In particular, claim 54 has been amended to specify that the multi-layer bioabsorbable collagenous biomaterial "comprises a material isolated from a warm-blooded vertebrate tissue source." A variety of such collagen-containing materials are in the current specification including submucosa, pericardium, liver tissue, basement membrane, and amniotic membrane (see, e.g., paragraphs [0033] and [0034]). The specification also teaches that suitable tissue materials can be isolated from the alimentary, integumentary, respiratory, urinary, and genital tracts of animals (see, e.g., paragraph [0039]). A person skilled in the art at the time the application was filed would have clearly recognized that the inventor was in possession of claim 54 in view of the disclosure of the application as filed.

With regard to the bonding together of multiple collagenous layer segments (e.g., to form a multi-layer device such as that shown in Figure 4), a variety of suitable bonding techniques and materials are described in the current specification.

Paragraph [0069] of the specification teaches that “strips can be fused to one another, for example by compressing overlapping areas of the strips under dehydrating conditions, to form an overall planar construct having a surface area greater than that of any one planar surface of the individual strips used to shape the construct.” This paragraph further states that “[s]hapes can be made by using sutures, staples, biocompatible adhesives such as collagen binding pastes, or dehydrating overlapping structures then heating the structure as described in U.S. Pat. No. 3,562,820.” The undersigned does not feel that the applicant should have been required to burden the specification with an exhaustive list of bonding techniques and materials. At the time the application was filed, it was known to those skilled in the art that collagenous material layers could be bonded together in a variety of fashions to form multi-layer devices.

Finally, with regard to the radiopaque marker being between the layers, the specification clearly states that in one embodiment “either the radiomarker 16 or pharmacologic agent 22, or both” can be “disposed in between the layers 20” (see paragraph [0090]).

For at least the reasons indicated, it is believed that claim 54 and its remaining dependent claims 55-60 and new claim 62 (claim 61 has been canceled) are fully supported by the written description provided in the present specification, and therefore, at the time the application was filed, the inventor had possession of the claimed subject matter. Reconsideration and withdrawal of these rejections are therefore solicited.

Claims 54-60 stand rejected under 35 USC § 112, based upon an assertion that the specification does not fully enable the claims. As discussed above, a variety of suitable collagenous materials and bonding techniques and materials are described in the specification (or were otherwise known in the art at the time the application was filed). It is not seen how one of ordinary skill in the art would have any undue difficulty in using the same to prepare a wide variety of multi-layer constructs in accordance with the invention of claim 54 as amended. Again, the Applicant is not required to burden the specification with an exhaustive description of manners in which to obtain collagenous materials and bond them together to form multi-layered constructs. A person skilled in the art at the time the application was filed would have clearly been able to make and use the invention of claim 54. As such, for at least the reasons indicated, it is believed that claim 54 and its dependent claims 55-60 and new claim 62 are fully supported by the specification from the standpoint of enablement, and withdrawal of this rejection is solicited.

Claims 36-45 and 53 stand rejected under 35 USC § 103(a) over a combination of U.S. Patent No. 6,444,229 to Voytik-Harbin et al. taken with U.S. Published Application No. 2004/0111149 A1 to Stinson. For the following reasons, reconsideration and withdrawal of this rejection are solicited.

Claim 36 requires an injectable chemotherapeutic composition that includes "a bioabsorbable collagenous biomaterial provided in an injectable form" and "a radiopaque marker component consisting essentially of a radiopaque powder material". In this rejection, the Examiner seems to be saying that the '229 patent to Voytik-Harbin teaches every element of claim 36 except a radiopaque powder

material, and that the '149 application to Stinson provides this "missing" element. However, according to MPEP § 2143.01, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). The '149 application to Stinson does not suggest the desirability of an *injectable* radiopaque composition.

While the '149 application to Stinson generally teaches adding a radiopaque marker to an implantable device, there is simply no teaching or suggestion to form an *injectable* composition having radiopacity. To the contrary, the '149 application specifically teaches away from forming such compositions.

The '149 application does not contain the terms "inject", "injectable", etc., and with regard to its "implantable endoprostheses", does not contain any terms that could be considered an equivalent thereof. Further, the '149 application often describes the radiopaque marker as being "disposed on or adjacent the endoprosthesis" and as "having a proximal end, a distal end, and a thickness" (see, e.g., paragraphs [0030] and [0031]). In paragraph [0065], the '149 application states, "[f]or description purposes, the markers of the invention can be segregated into types; threaded and discrete bioabsorbable-radiopaque markers. A threaded marker is generally a strand or strands of material having radiopacity which is incorporated within the implantable device by interweaving or interbraiding the strand through the struts or wires of the endoprosthesis. A discrete bioabsorbable-radiopaque marker is generally a bioabsorbable-radiopaque polymer strand of material which is securely attached to a localized region of the implantable device

and does not significantly extend over a large portion of the device.” The implantable devices described here are simply not *injectable* compositions, and therefore, neither of these radiopaque marker characterizations (i.e., “threaded” or “discrete”) lends itself in any way to a radiopaque marker consisting essentially of a radiopaque powder combined with an injectable material. As such, for at least the reasons indicated, it is submitted that independent claim 36 and claims 37-44 dependent thereon are patentably distinct from the combination of Voytik-Harbin and Stinson.

Independent claim 45 as amended requires "a spreadable radiopaque marker spread along the surface of the bioabsorbable collagenous biomaterial, said spreadable radiopaque marker consisting essentially of a radiopaque powder substance, wherein powder particles of said radiopaque powder substance are in contact with the surface of the bioabsorbable collagenous biomaterial". Support for this amendment can be found for example at page 27, lines 13-24 of the specification. Claim 53 depends upon claim 45 and therefore includes this feature as well. The Stinson reference does not teach or suggest such a feature, and in fact, teaches away from such a feature. The various radiopaque markers described in Stinson, for example, the mono-filaments, threads, ribbons, sutures, etc. (see, e.g., paragraph [0030]) are not spreadable along the surface of the implantable devices taught in the '149 application. Accordingly, withdrawal of the above-noted rejection as applied to claim 45 and 53 is also solicited.

Additional rejections under 35 USC § 103 are set forth beginning at pages 12 and 14 of the Office Action, respectively. In each of these cases, as above, the

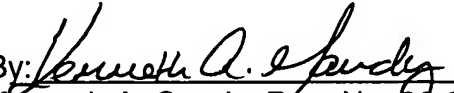
Stinson reference is relied upon with respect to its teachings of a radiopaque marker. However, as noted above, independent claim 45 and thus dependent claims 46-53 all incorporate the radiopaque marker in a manner distinct from the teachings of the Stinson reference, and in fact in a manner from which the Stinson reference teaches away. Withdrawal of these additional rejections under 35 USC § 103 is thus solicited.

New claim 62 has been added and introduces no new subject matter. Support is found for instance at page 21, lines 11-23. Allowance of this claim is solicited for the above reasons, at the least.

For the foregoing reasons, it is believed that this application is in condition for allowance containing claims 36-60 and 62. Action to that end is solicited.

The Examiner is asked to please telephone the undersigned attorney should there be any rejection that the Examiner believes could be maintained against the application as presently amended. Applicants' attorney would like the opportunity to telephonically interview the Examiner to try and arrive at acceptable claim language to proceed to allowance of the application.

Respectfully submitted,

By:   
Kenneth A. Gandy, Reg. No. 33,386  
Woodard, Emhardt, Moriarty  
McNett & Henry LLP  
Bank One Center/Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456